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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY/DOCKET NO. | CONFIRMATION NO. |
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| 09/671,104 | 09/27/2000 | Alan P. Kozikowski | ZAA-012.01 | 6012 |

25181 7590 05/05/2003

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

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| EXAMINER |
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HUANG, EVELYN MEI

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,104

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 27-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 27-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-18, 27-44 are pending. Claims 19-26, 45-59 have been canceled according to the amendment filed on 2-5-2003.

Priority

2. This application claims the benefit of 60/156275, filed on 9-27-1999. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112(2)

3. The amendment has obviated the 112 second paragraph rejection except for the issue set forth in the second part of paragraph 3c of the previous office action. Applicant has not addressed the groups hanging on the bivalent acyl, ether, sulfonyl, carbonyl, phosphoryl, amido, ester, etc., which are not described in the specification.

Claim Rejections - 35 USC § 112(1)

4. The 112 first paragraph rejection is maintained for reasons of record.

Applicant maintains that given the high level of skill in the monoamine art, the amended claims are adequately enabled. With the exemplification provided in the specification, one of ordinary skill in the art of synthetic chemistry would be able to make the compound without undue experimentation. Applicant further asserts that the specification has established that the

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inventive compounds inhibit the reuptake of monoamines, and therefore would be effective in treating a disorder caused by deficiency in the concentration of monoamine.

However, the scope of the claims must be commensurate with that of the objective enablement. Preparation of 8 example compounds is limited to A being a double bond, R1 is phenyl, substituted phenyl, naphthyl or furyl, R2 to R13 are hydrogen, R14 is a carboxylate (Fig. 3). These examples are very limited in comparison to the scope of the claims wherein R2 to R13 may be aryl, heteroaryl, cycloalkyl, polycyclic, heterocyclic etc. Undue experimentation would be required for the skill in the art to make these highly substituted compounds, (where the ring substituents are further substituted by bulky substituents), especially when the starting materials have not been disclosed.

The instant claims encompass compounds of vastly diverse structures. There is no assurance that such a diverse genus would have all the alleged activities in view of the high degree of unpredictability in the art. As monoamine includes norepinephrine (NE), serotonin (5-HT), dopamine (DA), each with its subtypes of receptors and are involved in functions similar or different from one another (Schildkraut, PTO-1449), and that structurally similar compounds have different selectivity (Kozikowski, column 59, Table 1; Scheel-Kruger, pages 17-18, Table 1), applicant's assertion that all these structurally diverse compounds would be effective in inhibiting *any* monoamine transporters, thereby useful for treating disorders or conditions caused by a deficiency in *any* type of monoamine concentration does not commensurate with the scope of the objective enablement. Furthermore, at present there is no umbrella drug that would treat all types of neurodegenerative diseases and all the different diseases recited in the instant claims. In the instant monoamine reuptake inhibitor art, where there is a high degree of unpredictability, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. In re Vaeck, 20 USPQ 2d 1438.

In conclusion, in view of the state of the art, the high degree of unpredictability of the art, the limited working examples, the scope of the claims does not commensurate with that of the objective enablement. Insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to practice the invention as claimed without undue experimentation except making and using the compounds of claims 5-6, 31-32 for

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inhibition of the reuptake of norepinephrine, serotonin, thereby useful for the treatment of depression, cocaine addiction etc.

Conclusion


5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

May 2, 2003